(2)

No. 85-478

OCT 18 1985

JOSEPH F. SPANIOL, JR.
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN SUPPORT OF PETITION FOR CERTIORARI

MILTON A. BASS
General Counsel
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017
(212) 838-3720

BEST AVAILABLE COPY

17pp

TABLE OF CONTENTS

	Page
INTEREST OF THE *AMICUS CURIAE*	1
ARGUMENT	2
USE BY GENERIC DRUG MANUFACTURERS OF THE SAME SIZE, SHAPE AND COLOR AS BRAND-NAME DRUGS LEGITIMATELY ASSISTS THE SAFE USE AND ACCEPTANCE OF GENERIC DRUGS AND PROVIDES LEGITIMATE BENEFITS TO PATIENTS AND HEALTH CARE PROFESSIONALS ...	2
A. The Unique Structure of the Pharmaceutical Industry	3
B. The Brand-Name Companies Are Not In Favor of Generic Competition	5
C. Color is Widely Used and Accepted as an Important Functional Element of Prescription Drug Appearance	6
CONCLUSION	11

TABLE OF CITATIONS

Cases Cited: **Page**

Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844 (1982) 9

Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960) 7

Statutes Cited:

Drug Price Competition and Patent Restoration Act of 1984, P.L. No. 98-417, 98 Stat. 1585, Sept. 24, 1984 4

21 C.F.R. §314.2 4

Other Authorities Cited:

Biron & Caringhan, *Chromo Confusion: A New Type of Pill-Pill 'Interaction' in Cardiology*, 110 CMA JOURNAL 1346-48 (June 22, 1974) 6

Blumenthal, Burke & Shapiro, *The Validity of Identical Matching Placebos*, 31 ARCH. GEN. PSYCH. 214 (Aug. 1974) 6

Capsugel . . . Introduces a New Color Series for Appearance and Effect . . . Luscher Palette (Parke-Davis, Divison of Warner-Lambert Co. 1982) 7-9

Capsule Color Considerations (Parke-Davis, Division of Warner-Lambert Co. 1980) 7

Competition in the Drug Industry: Hearings Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981) 3

	Page
Competitive Problems in the Drug Industry: Hearings before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business (93rd Cong., 2d Sess. 1974)	3
Dichter, *Handbook of Consumer Motivations*, 228 (1964)	7
Drug Product Selection, Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979)	3
47 F.R. 444, 447 col. 2 (Jan. 5, 1982)	7
F-D-C Reports, T&G-2 Sept. 9, 1985	10
Gowdy, et al., *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96 CAN.MED. ASS'N J. 1317, 1320 (1967)	6
Improving Medication Compliance, Summaries of Symposium Presentation (November 1984)	9-10
Jacobs & Nordan, *Classification of Placebo Drugs: Effect of Color*, 49 PERCEPTUAL & MOTOR SKILLS 367-372 (1979)	6
Leslie, *Ethics and Practice of Placebo Therapy*, 16 AM.J.MED. 854, 859 (1954)	7
Note, *Consumer Protection and Prescription Drugs: The Generic Drug Laws*, 67 KY.L.J. 384 (1978-79)	4
Plevan & Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. L.J. August 12, 1985	10

Page

Prescription Drug Labeling and Price Advertising, Hearings Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce (94th Cong., 2nd Sess. April 22, 1976) 10

Rados, *FDA Consumer* (October 1985) 3, 5

Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978) 3

Schapira, *et al.*, *Study on the Effects of Tablet Colour in the Treatment of Anxiety States* 2 BRIT. MED.J. 446-449 (1970) 6

Schwartz, *The Elderly Patient and His Medications*, GERIATRICS, 517 (June 1965) .. 7

Trouton, *Placebos and Their Psychological Effect*, 103 J.MENTAL SCI. 344 (1957) 7

Washington Drug Letter, Vol. 17, No. 38 (Sept. 23, 1985) 5-6

No. 85-478

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

PAR PHARMACEUTICAL, INC.,

Petitioner,

vs.

MERCK & CO., INC.,

Respondent.

BRIEF OF *AMICUS CURIAE* NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN SUPPORT OF PETITION FOR CERTIORARI

INTEREST OF THE AMICUS CURIAE

The National Association of Pharmaceutical Manufacturers ("NAPM") respectfully submits this *amicus curiae* brief in support of the petitioner Par Pharmaceutical, Inc. ("Par"). NAPM requests that the Court grant the petition for certiorari to resolve the still ongoing dispute between brand-name and generic drug manufacturers over product appearance.

NAPM is a national trade association representing more than 100 manufacturers and distributors of multi-source prescription and over-the-counter drug products, veterinary drugs, and vitamins and other dietary supplements. Since 1955, NAPM has been the leading voice for what is commonly known as the generic drug industry. In this capacity, NAPM has appeared in the courts as an *amicus* and as a party, including participation as *amicus* in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982). NAPM has also appeared before administrative tribunals, has regularly participated in U.S. Food and Drug Administration ("FDA") rulemaking procedures, and frequently appeared in hearings before Congress and state legislatures. NAPM has sponsored educational seminars, bringing together representatives of the pharmaceutical industry with the scientific and legal community, as well as officials of FDA and the Drug Enforcement Administration. NAPM has also been responsible for development of the solid dosage form identification system for over 600 drugs. Petitioner Par, one of the leading generic drug manufacturers, is a member of NAPM.[1]

ARGUMENT

USE BY GENERIC DRUG MANUFACTURERS OF THE SAME SIZE, SHAPE AND COLOR AS BRAND-NAME DRUGS LEGITIMATELY ASSISTS THE SAFE USE AND ACCEPTANCE OF GENERIC DRUGS AND PROVIDES LEGITIMATE BENEFITS TO PATIENTS AND HEALTH CARE PROFESSIONALS

This case involves the role of generic prescription drugs in the national system of health care. Brand-name companies would prefer that smaller generic competitors not exist; short

[1] The General Counsel of the NAPM is a member of the firm which represents petitioner Par.

of that, efforts of the large brand-name companies have been directed to impeding the acceptability of generic drugs in the marketplace. The "size, shape and color" issue is the product of such an effort.

A. The Unique Structure of the Pharmaceutical Industry

At the root of the dispute raised by Par's petition for certiorari are certain commercial realities. The most significant of the realities is that Par and other generic manufacturers sell their products for far less than do brand-name companies. Report of New York State Assembly Office of Legislative Oversight and Analysis, *Are Generics Safe?* (June 23, 1978); Rados, *FDA Consumer* (October 1985). This dual pricing structure operates at both the wholesale and retail level — pharmacists pay less for generic drugs, and patients in turn realize substantial savings when the pharmacist dispenses a generic drug. In addition, the success of generic drug competition serves as a market force reducing the price of brand-name drugs themselves. Thus, obstacles to generic competition not only enhance the volume of brand-name business, but also increase the per unit profitability of brand-name companies. *Competitive Problems in the Drug Industry*: Hearings before the Subcomm. on Monopoly of the Senate Select Comm. on Small Business, at 10, 268 (93rd Cong., 2d Sess. 1974); *Drug Product Selecton*, Staff Report to the Federal Trade Commission (Bureau of Consumer Protection, Jan. 1979); *Competition in the Drug Industry*: Hearing Before the Subcomm. on Oversight and Investigations of the House Committee on Energy and Commerce (97th Cong., 1st Sess., Mar. 10, 1981).

The role of generic drugs is therefore of tremendous importance. Approximately 20 billion dollars per year are involved. The elderly and the poor are hit particularly hard by the high prices charged by brand-name companies. In addition, such price differentials are implicated in government purchase cost-containment programs. The burden of paying for brand-name drugs in such circumstances falls on taxpayers generally. In short, the lower prices for generic drugs can result in savings

of millions of dollars in the containment of health care costs of consumers, the federal government, Medicare and Medicaid programs, the armed services, including the Veterans Administration, state and local governments, and private hospitals.

Another major reality in the prescription pharmaceutical industry is that the ultimate user of the product plays almost no role in selecting the product. Because state and federal laws prohibit consumer use without a prescription, it is the physician who chooses the drug product. In this unique market, Merck and other brand-name companies engage in extensive advertising directed to physicians, not consumers.

The final significant reality in this industry is the nature of government regulation. Before the mid-1970's, a prescription written in the brand-name of the product could be filled only with that brand. In 1972, 47 states had such antisubstitution laws.

Recognizing that promotional efforts during patent life tended to obscure the generic names of pharmaceuticals, and the habit of physicians to identify a product by its brand name, the states began enacting substitution statutes. These statutes encourage generic substitution by setting forth those circumstances where a generic product may, or must, be dispensed, even if the physician has written the prescription by using the brand name. *See, e.g.*, Note, *Consumer Protection and Prescription Drugs: The Generic Drug Laws*, 67 KY.L.J. 384 (1978-79).

By way of recent statutory amendments, generic drug manufacturers may now generally obtain FDA approval under an abbreviated process. 21 C.F.R. §314.2 (superceded); Drug Price Competition and Patent Restoration Act of 1984, P.L. No. 98-417, 98 Stat. 1585, Sept. 24, 1984. FDA must still approve these products as safe and effective based upon scientific substantiation, but without the submission of reports of unnecessary and duplicative testing.

These changes in government regulation evidence a philosophy by Congress, FDA and all 50 states encouraging generic substitution. FDA has recently noted:

> "[T]he potential for reducing U.S. health-care costs through wider availability of generic drugs prompted Congress to pass the law last year that streamlined FDA's approval process for generics. When President Reagan signed the law, he noted that 'the American people will save money, and yet receive the best medicine that pharmaceutical science can provide.' " Rados, *FDA Consumer* (October 1985).

Merck and the brand-name industry want to derail this philosophy by misusing the trademark laws to impose a stigma upon generic drugs.

B. The Brand-Name Companies Are Not In Favor of Generic Competition

The brand name companies have generally contended that they do not oppose generic competition, only unfair generic competition. Economic reality and the pattern of behavior by the brand-name industry belie this contention.

In the 1970's, the brand-name pharmaceutical industry led the fight against passage of substitution laws. Now that these laws have been passed in all 50 states, and in the District of Columbia and Commonwealth of Puerto Rico, it is axiomatic that these laws have served as a stimulus to substantial savings to consumers.

The focus of brand-name efforts against generic competition have now shifted from the legislative arena to the marketplace. A principal method is product disparagement. Sandoz, for example, has marketed a product called Mellaril[R] for many years. Faced with generic competition, Sandoz placed numerous advertisements disparaging the quality of generic substitutes. In response, FDA has recently directed Sandoz to discontinue such activities and informed Sandoz that:

> "[Y]our continued use of misleading promotional materials and your activities aimed at discrediting

competing thioridazine products without scientific basis are flagrant, repeated and willful violations of the FD&C Act." *Washington Drug Letter*, Vol. 17, No. 38 (Sept. 23, 1985).[2]

The "size, shape and color" issue is another example of efforts to thwart generic competition. In this case, for example, Merck conducted a study of the effect of appearance on substitution rates. Merck's goal was to create "a strategy to reduce the impact of generic competition . . ." The study recommended the use of different appearances between brand-name and generic drugs, not to prevent illegal substitution, but "on the theory that patients would be upset if an unfamiliar pill was substituted for a familiar one."

C. Color is Widely Used and Accepted as an Important Functional Element of Prescription Drug Appearance

Par has presented evidence in this case consisting of expert witnesses and Merck documents which show the functionality of capsule colors. The fact of the functionality of capsule colors is widely known in the pharmaceutical industry. It has been shown that the "placebo" effect which is inherent in any drug, and indeed some aspects of a drug's efficacy, are related to the color configuration of a given product. *See generally*, Schapira, *et al., Study on the Effects of Tablet Colour in the Treatment of Anxiety States* 2 BRIT. MED.J. 446-449 (1970); Jacobs & Nordan, *Classification of Placebo Drugs: Effect of Color*, 49 PERCEPTUAL & MOTOR SKILLS 367-372 (1979); Blumenthal, Burke & Shapiro, *The Validity of Identical Matching Placebos*, 31 ARCH.GEN.PSYCH 214 (Aug. 1974); Biron & Caringhan, *Chromo Confusion: A New Type of Pill-Pill 'Interaction' in Cardiology*, 110 CMA JOURNAL: 1346-48 (June 22, 1974); Gowdy, et al., *A Controlled Clinical Trial Using Placebos in Normal Subjects: A Teaching Exercise*, 96

[2] Searle has also recently engaged in a pattern of advertising intended to disparage the quality of FDA-approved generic substitutes for Norpace®.

CAN.MED. ASS'N J. 1317, 1320 (1967); Schwartz, *The Elderly Patient and His Medications*; GERIATRICS, 517 (June 1965); Dichter, *Handbook of Consumer Motivations*, 228 (1964); Trouton, *Placebos and Their Psychological Effect*, 103 J.MENTAL SCI. 344 (1957); Leslie, *Ethics and Practice of Placebo Therapy*, 16 AM.J.MED. 854, 859 (1954). *Cf.*, 47 F.R. 444, 447 col. 2 (Jan. 5, 1982) (FDA panel notes that major drawback in use of activated charcoal as antitoxin is its black color, which often causes children to refuse it). *See also Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F.2d 569, 572 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960).

Indeed, brand-name drug companies themselves recognize this aspect of color functionality. The leading manufacturer of pharmaceutical capsules is Parke-Davis, which has extensively promoted the functionality of capsule colors in two publications entitled: *Capsule Color Considerations* (Parke-Davis, Division of Warner-Lambert Co. 1980) ("Parke-Davis 1980") and *Capsugel . . . Introduces a New Color Series for Appearance and Effect . . . Luscher Palette* (Parke-Davis, Division of Warner-Lambert Co., 1982) ("Parke-Davis 1982"). In Parke-Davis 1980, it states:

> *"Parke-Davis Can Provide you with the 'Color Edge'*
>
> Our color laboratory, our equipment and our color experts are at your command to come up with the right colors for you. Contact our technical sales representative. Show him the color combination you have in mind .... If you need guidance in psychologically appropriate colors, we can provide several papers on the subject. Better still, let our color consultants come up with a few suggestions."

In another promotional piece, Parke-Davis sets forth the color strategies to be utilized by drug manufacturers. As described by Professor Max Luscher, the world's foremost authority on the psychology of color:

"The Choice of Appropriate Capsule Colors

In traffic signs, color is recognized by everybody as a signal, as it is in clothing as well as in packages such as capsules. Every signal exerts an effect. Most of them – as for instance the red stop light and dress colors – exert their effect without the observer realizing he has consciously taken note. The action of a pharmaceutical preparation should be recognizable from the color in exactly the same way. It is the function of the color of a capsule to transmit the correct signal.

* * *

Two-color capsules, on the other hand, where the two parts have different colors, indicate a change from one condition to another, namely from a state of illness to one of effective therapy. If one part of the capsule is red, irritation and inflammation are indicated, whereas a dark blue color of the other part represents the sedation which the preparation is aimed to achieve.

Since one color alone indicates only a general property, whereas two are a sign of a special one, most firms – and products – characterize their image with at least two colors. The same applies to preparations put up in capsules. With two colors, identification becomes much more accurate.

* * *

It is obvious, however, that a preparation will be taken more regularly if it is packaged in a color the patient finds pleasant and suggestive of a favorable effect.

* * *

> . . . [t]he following examples of functional color combinations will furnish an idea of which color effect is appropriate for a desired therapeutic effect.
>
> The colors chosen are most effective when they clearly express the action of the preparation; this functional aspect has priority . . ."

Parke-Davis 1982 at 3.

The precedent of this Court, *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844 (1982), the evidence in this case, and common sense establish both the existence and the importance of the functional role of color. If, for example, one opened up a new bottle thought to contain aspirin, but found green tablets, one would think that the product was not aspirin. It is not at all a question of source, but of product identification. In this case, all the experts likewise testified that patients frequently think a mistake had been made when they received unfamiliar pills, but usually appeared to accept the explanation that a generic was dispensed. If such patient confusion was produced because they thought they were getting a different brand of the same medicine, they would hardly be relieved to learn that they were getting a generic substitute.

NAPM takes strong issue with the viewpoint that the advantages fostered by the use of the same size, shape and color for prescription drugs are "minimal" for any reason.

Some generic manufacturers now choose not to imitate product appearance. When they decline to imitate, patients and health care professionals are deprived of the tools that assist in proper compliance and product identification. NAPM believes that patient compliance is a vitally important issue facing health care today. Indeed, the President of the National Pharmaceutical Council, an arm of the brand-name drug industry, has himself characterized noncompliance as a "major public

health problem." *Improving Medication Compliance*, Summaries of Symposium Presentation (November 1984). Continuity of color in the dispensing of prescription drugs can only be an instrument of assistance to physicians, nurses, pharmacists, and patients in solving this problem:

> "Also, as there is always a certain amount of apprehension about taking medications, even those prescribed by a trusted physician, imagine the problems that would be created when the blood pressure pills are one month pink and the next month white and when those that were round one month are the next month rectangular, square or octagonal. The anxiety produced by repeated exposure to unfamiliar size, shape, and color would be sufficient to cause some people to discontinue their treatment program either in whole or in part. I need not detail the damage and even deaths that would result as a consequence of this particular problem." Testimony of Lawrence A. Tillis, M.D., *Prescription Drug Labeling and Price Advertising*, Hearings Before the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce at 176 (94th Cong., 2nd Sess. April 22, 1976).

NAPM believes it is unwise to penalize Par and the users of its product by denigrating the legitimate advantages of imitation as minimal. The brand-name industry's attempt to stigmatize generic drug products by imposing color changes will finally succeed absent intervention by this Court. Indeed, industry and legal commentators have pointed to the need for resolution by this Court as the controversy continues to grow. Plevan & Siroky, *The 3d Circuit Gets a Dose of Suits Filed Against 'Look-Alike' Drugs*, Nat. L.J. August 12, 1985; *F-D-C Reports*, T&G-2 Sept. 9, 1985.

If the brand-name companies continue to be successful in using the Lanham Act to extend their patent monopolies to the appearances to which the public is accustomed, patients and

health care professionals will be deprived of the undisputed legitimate advantages of trade dress imitation. NAPM respectfully believes that this threat to effective competition in the pharmaceutical industry is of vital importance to its members and to the public, and that certiorari is needed to resolve these issues.

CONCLUSION

It is respectfully submitted that a writ of certiorari be issued to the United States Court of Appeals for the Third Circuit as requested by Par Pharmaceutical, Inc.

Respectfully submitted,

MILTON A. BASS
General Counsel
National Association of Pharmaceutical Manufacturers
747 Third Avenue
New York, New York 10017
(212) 838-3720

Of Counsel:
LAWRENCE H. ROTH